Novartis launches Arcapta™ Neohaler™, a novel once-daily bronchodilator for chronic obstructive pulmonary disease

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- - Arcapta Neohaler is the only once-daily, 24-hour long-acting beta2-agonist approved for maintenance treatment of airflow obstruction in COPD patients
- - Arcapta Neohaler showed significant improvements in lung function (FEV1) lasting 24 hours; FEV1 improvements were seen at 5 minutes after first dose
- - Arcapta Neohaler is approved with data demonstrating improvements in health-related quality of life
- - COPD is a progressive and life-threatening lung disease that affects more than 14 million Americans and is a major cause of long-term disability

EAST HANOVER, N.J., March 19, 2012 /PRNewswire/ -- Novartis Pharmaceuticals Corporation today announced that once-daily Arcapta™ Neohaler™ (indacaterol inhalation powder) 75 mcg is now available in the US and in pharmacies nationwide.

Arcapta Neohaler is indicated for the long-term maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Arcapta Neohaler is not indicated to treat asthma. It is also not indicated to treat acute deteriorations of COPD and should not be used as a rescue medication for acute symptoms.

Arcapta Neohaler is the only once-daily, 24-hour long-acting beta2-agonist (LABA) approved in the US for maintenance treatment of airflow obstruction in patients with COPD. Arcapta Neohaler is an inhaled, steroid-free COPD treatment.

Arcapta Neohaler 75 mcg was studied in a total of 641 COPD patients in two key Phase III trials lasting 12 weeks. The primary endpoint results at week 12 showed that Arcapta Neohaler significantly improved lung function (FEV1) at 24 hours compared to placebo. As a secondary endpoint, lung function (FEV1) improvements were seen at five minutes after the first dose compared to placebo, and improvements observed at week 4 were consistently maintained over the course of 12 weeks in both trials.

"Arcapta Neohaler represents an important new treatment option for the 14 million Americans living with COPD," said Andre Wyss, President, Novartis Pharmaceuticals Corporation. "The launch of Arcapta Neohaler is a significant milestone as we continue to establish a strong respiratory presence in the US market."

COPD is a common, preventable and treatable disease characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways of the lungs to noxious particles or gases. More than 14 million people in the US are affected, while another estimated 12 million people are believed to have the disease but remain undiagnosed. COPD ranks as the third leading cause of death in the US and is a major cause of serious long-term disability. Arcapta Neohaler has not been shown to impact mortality or long-term disability caused by COPD.

According to 2011 GOLD Guidelines, bronchodilators are central to COPD management. Bronchodilators have

different mechanisms of action and long-acting beta2-agonists (LABA) are among the classes of bronchodilators.

"The COPD Foundation is dedicated to providing information and support individuals with COPD," said John W. Walsh, president and co-founder of the US-based COPD Foundation. "The availability of this new, once-daily LABA is good news for COPD patients looking for new treatment options and for the millions of Americans that are living with this serious disease."

Once-daily Arcapta Neohaler also reduced the need for patients to use short-acting beta2-agonists (albuterol) as rescue therapy, measured as a secondary endpoint. Additionally, Arcapta Neohaler is the only COPD treatment approved with demonstrated improvements in health-related quality of life, as measured by the St George's Respiratory Questionnaire (SGRQ). The SGRQ is a disease-specific, patient-reported instrument that measures health-related quality of life for symptoms, activities and impact of daily life.

The safety and tolerability of Arcapta Neohaler was assessed in a clinical program of more than 5,400 COPD patients, with more than 2,500 who received Arcapta Neohaler for at least 12 weeks at doses of 75 mcg or higher. Adverse reactions were reported by 48% of patients treated with any dose of Arcapta Neohaler compared with 43% of patients treated with placebo. The most common serious adverse reactions were COPD exacerbation, pneumonia, angina pectoris, and atrial fibrillation, which occurred at similar rates across treatment groups.

Indacaterol was first approved in November 2009 in the European Union under the brand-name Onbrez® Breezhaler®. It is now approved in more than 80 countries for the treatment of COPD, and is available in more than 30 countries with additional launches planned during 2012.

Important Safety Information

WARNING: ASTHMA-RELATED DEATH

Long-acting beta2-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta2-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including indacaterol, the active ingredient in Arcapta Neohaler. The safety and efficacy of Arcapta Neohaler in patients with asthma have not been established. Arcapta Neohaler is not indicated for the treatment of asthma.

All LABA are contraindicated in patients with asthma without use of a long-term asthma control medication.

Arcapta Neohaler should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition, or used as rescue therapy for acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta2-agonist.

Arcapta Neohaler should not be used more often, at higher doses than recommended, or in conjunction with other medications containing long-acting beta2-agonists as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

Arcapta Neohaler may produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, Arcapta Neohaler should be discontinued immediately and alternative therapy instituted.

Arcapta Neohaler can produce a clinically significant cardiovascular effect in some patients, as measured by

increases in pulse rate, systolic or diastolic blood pressure, or symptoms, and should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Arcapta Neohaler should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

The most commonly reported adverse reactions in patients taking Arcapta Neohaler (>2% and higher than placebo) were cough (6.5%), nasopharyngitis (5.3%), headache (5.1%), nausea (2.4%), and oropharyngeal pain (2.2%).

Arcapta Neohaler should be used with extreme caution in patients treated with monoamine oxidase inhibitors, tricyclic antidepressants, or other drugs known to prolong the QTc interval because the action of adrenergic agonists on the cardiovascular system may be potentiated.

Arcapta Neohaler should be used with caution in patients treated with additional adrenergic drugs, non-potassium-sparing diuretics, and beta-blockers.

Arcapta capsules must not be swallowed as the intended effects on the lungs will not be obtained. Arcapta capsules are only for oral inhalation and should only be used with the Neohaler device. The Neohaler device should not be used with any other capsules.

Please see full Prescribing Information, including BOXED WARNING at http://www.pharma.us.novartis.com/product/pi/pdf/arcapta.pdf or contact Christine Cascio at 862-778-8026 or christine.cascio@novartis.com.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "launches," "launch," "milestone," "continue," "planned," or similar expressions, or by express or implied discussions regarding the potential development and marketing of potential future respiratory products, regarding potential future launches of indacaterol, or regarding potential future revenues from indacaterol. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis will successfully develop or bring to market any additional respiratory products. Nor can there be any guarantee that indacaterol will be launched in any particular countries, or at any particular time. Neither can there be any guarantee that indacaterol will achieve any particular levels of revenue in the future. In particular, management's expectations regarding indacaterol could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including unexpected reimbursement difficulties or delays; competition in general; government, industry and general public pricing pressures; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future

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About Novartis

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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